

Serial No. 09/868,974

Amendments to the Claims

1-33 (cancelled)

34. (amended) A shelf-stable solution formulation comprising a therapeutically effective amount of a glucagon-like peptide-1 (GLP-1) molecule, a pharmaceutically acceptable preservative and a tonicity modifier, wherein the formulation has a pH that is about 8.2 to about 8.8, and wherein the molecule comprises the same amino acid sequence as a molecule selected from the group consisting of GLP-1(7-34), GLP-1(7-35), GLP-1(7-36), GLP-1(7-37), or the amide forms thereof, and at least one modification selected from the group consisting of:
- (a) substitution of a glycine, serine, cysteine, threonine, asparagine, glutamine, tyrosine, alanine, valine, isoleucine, leucine, methionine, phenylalanine, arginine, or D-lysine for lysine at position 26 and/or position 34 or substitution of a glycine, serine, cysteine, threonine, asparagine, glutamine, tyrosine, alanine, valine, isoleucine, leucine, methionine, phenylalanine, lysine, or a D-arginine for arginine at position 36;
 - (b) substitution of an oxidation-resistant amino acid for tryptophan at position 31;
 - (c) substitution of at least one of: tyrosine for valine at position 16; lysine for serine at position 18; aspartic acid for glutamic acid at position 21; serine for glycine at position 22; arginine for glutamine at position 23; arginine for alanine at position 24; and glutamine for lysine at position 26; and
 - (d) substitution comprising at least one of: glycine, serine, or cysteine for alanine at position 8; aspartic acid, glycine, serine, cysteine, threonine, asparagine, glutamine, tyrosine, alanine, valine, isoleucine, leucine, methionine, or phenylalanine for glutamic acid at position 9; serine, cysteine, threonine, asparagine, glutamine, tyrosine, alanine, valine, isoleucine, leucine, methionine, or phenylalanine for glycine at position 10; and glutamic acid for aspartic acid at position 15;
- ~~a pharmaceutically acceptable preservative, and a tonicity modifier, wherein said formulation has a pH that is about 8.2 to about 8.8.~~

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35. (cancelled)
36. (previously amended) The formulation of claim 34, wherein arginine is substituted for lysine at position 34.
37. (previously presented) The formulation of claim 34 wherein the formulation is buffered by TRIS.
- 38-39. (cancelled)
40. (previously presented) A method for treating diabetes comprising administering to a patient in need of such treatment an effective amount of the formulation of claim 34.
41. (previously presented) A shelf-stable solution formulation comprising a therapeutically effective amount of a glucagon-like peptide-1 (GLP-1) molecule which comprises the amino acid sequence:
R₁-X-Glu-Gly¹⁰-Thr-Phe-Thr-Ser-Asp¹⁵-Val-Ser-Ser-Tyr-
Leu²⁰-Y-Gly-Gln-Ala-Ala²⁵-Lys-Z-Phe-Ile-Ala³⁰-Trp-Leu-Val-
Lys-Gly³⁵-Arg-R₂ (SEQ ID NO:2)
wherein R₁ is His or desamino-histidine, X is Ala, Gly or Val, Y is Glu or Gln, Z is Glu or Gln and R₂ is Gly-OH;
a pharmaceutically acceptable preservative; and a tonicity modifier,
wherein said formulation has a pH that is about 8.2 to about 8.8.
42. (cancelled)
43. (previously presented) The formulation of claim 41, wherein R₁ is L-histidine, X is Val, Y is Glu, Z is Glu, and R₂ is Gly-OH.
44. (previously presented) The formulation of claim 41 wherein the formulation is buffered by TRIS.
- 45-46. (cancelled)
47. (previously presented) A method for treating diabetes comprising administering to a patient in need of such treatment an effective amount of the formulation of claim 41.